a supplement to *Clinical Lab Products* 

# CLINICAL LAB PRODUCTS

Our annual profile of some of the industry's top clinical lab professionals.

# CERTICAL LAB PROFESSIONALS

A national directory of clinical lab professionals committed to excellence.

# **Helping Patients and Peers**

"Although rudimentary examinations of human body fluids date back to the time of the ancient Greek physician Hippocrates around 300 BC, it was not until 1896 that the first clinical laboratory was opened, a twelve-foot-by-twelve-foot room equipped at a cost of \$50 at Johns Hopkins Hospital," writes Frances A. Delwiche, MLIS, MT (ASCP), in a 2003 paper titled "Mapping the Literature of Clinical Laboratory Science." "At that time," he writes, "most 'laboratories' consisted of little more than a corner in physicians' homes, offices, or hospital wards, with physicians performing the procedures themselves. The diagnostic and therapeutic value of laboratory testing was not yet appreciated, and many physicians viewed clinical laboratories simply as an expensive luxury that consumed both valuable space and time."

Clinical labs today are an essential expensive necessity, staffed with consummate professionals and

equipped with cutting-edge technology. The sheer volume of information, technology, and regulations lab professionals must manage is mind-boggling. Their prestige has grown since olden times, toowith U.S. News & World Report's "Best 50 Careers of 2011" naming medical technologists and clinical laboratory scientists as top, in-demand careers, and calling these individuals "the unsung heroes of the healthcare industry."

Clinical Lab Products salutes these individuals with our Best of 2011 Clinical Lab Professionals.

We invited readers from labs nationwide to tell us how they strive for excellence and achieve it. The following pages tell their stories

David Tacha, HTL (ASCP), PhD, vice president of R&D, chief scientific officer, Biocare Medical, Concord, Calif, is one of the founders of the company, which has become known as an innovator in immunohistochemistry (IHC) technology.

Rochelle P. Stewart, MBA, CLS, М L S ( A S C P ) <sup>С м</sup>. OLC(ASCP), CLC/ MT(AMT), founder, president, and CEO, RPL Laboratory Solutions Inc, a laboratory



consulting firm, helps clients navigate convoluted state and federal regulatory and accreditation requirements for waived and nonwaived lab testing.

Their stories resonate with their commitment to excellence.

Judy O'Rourke Editor, CLP jorourke@allied360.com (619) 659-1065

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# Biocare's Legacy: Diagnostic Power Through Multiplex IHC

### **BY JL SILVERMAN**

When you walk into the lab of David Tacha, HTL (ASCP), PhD, vice president of R&D, chief scientific officer, Biocare Medical, Concord, Calif, you see photographs of famous people: John Wayne, Shirley Temple, and Lance Armstrong—people who were cancer survivors or who have died of cancer. Each picture serves as a reminder that everything done at Biocare Medical is for the patients. It is instilled into every employee that the awareness of the fact that behind every slide is a human being. This is the powerful driving force within the company.

Tacha co-founded Biocare Medical in 1997 with Roy Paxton Yih and Gene Castagnini, all present owners of the company. Their objective was to form a new company with strong foundations in tech support and education. Biocare has become known as an innovator in immunohistochemistry (IHC) technology.

"We believed that there was a lack of not just troubleshooting technical problems, but of giving out information of a purely educational basis," Tacha says. "The Biocare Education Center was developed for people to receive continuing education. We wanted to develop equipment and reagents through strong R&D innovation."

One of the things the company is proud of is the invention developed around Multiplex IHC products or double stains. For a double stain, they were able to put two, three, or four antibodies onto a single tissue section and see morphology and color, looking at one slide instead of three to four slides. Multiple slides create the problem of sequential viewing and limited tissue.

In 2003 and 2004 there had yet to be a ready-to-use double stain kit that was suitable for clinical applications, something reproducible, labeled IVD for reimbursement, and that could be used on an automated staining system. "We were the first company in the United States that actually developed a double-stain primary antibody with a double-stain detection kit that could be used for routine diagnostic procedures," Tacha says. "But we took this one step further ...

"We not only took the double stain so that you could see two different antibodies or two different types of diagnosis, but we now started color coding cancer cells," Tacha adds. "So what





Biocare Medical's innovations are grounded in patient care, says David Tacha, HTL (ASCP), PhD, vice president of R&D, chief scientific officer, and one of the company's founders.

we did—and this is the key that makes it totally unique to any double stain that has ever been done—is that we would label compartments of tumor cells, or tumor structures with colors. We made a 'spectral fingerprint.' " Pathologists could now see the difference between something that was benign or something that potentially was malignant cancer: a spectral fingerprint based on colors and morphology.

The only double stains that had ever been done before were in research labs—using a sequential detection, and taking a long time to process. Biocare's system can process up to five antibodies on a single slide in less than 3 hours. Not only does this save money, time, and limited tissue, but even more important is now the spectral fingerprint is part of the diagnostic procedure.

Every Multiplex IHC is unique. These "fingerprints" give pathologists the assurance that their diagnosis is accurate, and helps oncologists properly treat their patients—especially those with a difficult diagnosis such as breast, bladder, or prostate cancer. Multiplex IHC is now being used on a routine basis as a spectral fingerprint that is used everywhere from community hospitals to university hospitals.

Biocare's Multiplex IHC tests—PIN-4, ADH-5, Uro-3, and the most recent innovation called the PulmoPanel, used for differentiation of squamous versus adenocarcinoma in non-small cell lung cancer diagnosis—are used primarily in hospitals and university hospitals. However, this is no longer purely research; they are routinely used as a clinical application. "The beauty of our diagnostic kits is that they can be used on other people's platforms," Tacha says.

What separates Biocare from other companies is the very strong need to continue to push the envelope of innovation, Tacha says. He once asked a famous pathologist, "What keeps you up at night? 'This is my dilemma,' [he told me]: 'I'm doing the best I can, but I know that I don't have the proper tools to give accuracy 100% of the time. As a pathologist who cares about his patients,

that keeps me up at night.' It keeps me up at night, too.

"Everyone has a stainer and antibodies," Tacha continues. "What can this company do that will have a stronger impact on patient care? What will give more diagnostic power? Now I can go home and say thousands of patients got an accurate diagnosis because of the work that we've done at Biocare."

This is a true success story of a small entrepreneurial company. Biocare Medical has become a market leader in simultaneous Multiplex IHC. It is quickly and freely moving innovation forward. "We have competed with the giants, and we have created new technology that they can only copy," Tacha says.

"It's kind of interesting. When I was at BioGenex, I used to be Roy Yih's boss, and now he's my boss," Tacha continues. "But Roy feels the same way. Patient care burns in his soul: It's instilled in him that when we sell an antibody, it's not just going on a slide. There's a patient behind the slide. When we say 'One slide at a time,' it's like one patient at a time. And this has driven these innovations."

JL Silverman is a contributing writer for CLP.

**Biocare Medical** 4040 Pike Lane Concord, CA 94520 (800) 799-9499 www.biocare.net



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Norman Clinical

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Laboratory Inc

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Sandusky, Ohio (419) 626-6012

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Hospital

Center Gainesville, Tex (940) 665-1751

Paris, Ark (479) 963-6101

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Burlington, Iowa (319) 752-8422

North Logan Mercy

North Texas Medical

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Northeastern Lab

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# RPL Helps Labs Navigate Complex Requirements for Lab Testing

### BY SARAH MICHAUD

RPL Laboratory Solutions<sup>®</sup> Inc (RPL), Riverside, Calif, is a laboratory consulting firm with more than 25 years of experience helping clients throughout the nation navigate complex state and federal regulatory and accreditation requirements for waived and nonwaived lab testing.

RPL's extensive and diverse client base ranges from single-practice physician office laboratories to full-service reference laboratories.

Whether the governing body is state, federal, Commission on Office Laboratory Accreditation, Joint Commission on Accreditation of Health Care Organizations, or College of American Pathologists, RPL will design, implement, and manage comprehensive compliance programs customized to the client's specific needs, freeing them to concentrate on growing a successful business. To accomplish this, RPL works with clients to understand how they want to do business, and then formulates a plan, executes it, and provides a working laboratory management program that can grow with them as their lab expands to ensure future success.

A visit to RPL's Web site (www.rplLaboratorySolutions.com) illustrates the company's ability to provide a one-stop shop for all lab regulatory, compliance, and operation needs. RPL's staff is comprised of licensed professionals with more than 100 years of collective experience who are dedicated to working with clients and assisting them with all facets of operations and management. Staff members are available on-site or by remote access to simplify the regulation and accreditation process. RPL's staff understands that sharing information is the key to fostering an environment of trust in RPL's expertise. The company has retained clients for decades using this unique and collaborative approach.

RPL's products and services have been validated continuously by regulatory agencies since 1986. Whether a new or established lab, by following RPL's program, clients have unanimously achieved successful inspection outcomes.

Rochelle P. Stewart, MBA, CLS, MLS(ASCP)<sup>CM</sup>, QLC(ASCP), CLC/ MT(AMT), is the founder, president, and CEO of RPL. Ms Stewart's extraordinary passion for and commitment to her work has led to a vast breadth and depth of experience and knowledge of the industry. Her areas of expertise include laboratory medicine, practice management, and safety. She served as an Expert Clinical Laboratory Improvement Amendments (CLIA) Surveyor for the Centers for Medicare & Medicaid Services (CMS); an American Medical Technologist (AMT) committee member for the Laboratory Consultant Certification Program; and an AMT committee member for the Certified Office Laboratory Technician's Education, Qualifications, and Standards Committee.

# **RPL Laboratory Solutions® Inc**



Rochelle P. Stewart, MBA, CLS, MLS(ASCP)<sup>CM</sup>, QLC(ASCP), CLC/MT(AMT) (bottom row, at right), and members of the Southern California team.

### **EVOLUTION OF RPL**

Ms Stewart started her consulting work after she was sought out by vendors and manufacturers who recognized the high-quality standards she maintained in her labs. CLIA '88 was emerging and impacting their client physicians. She was able to apply her expertise and provide solutions for these troubled labs.

During her tenure as an expert CLIA surveyor for CMS, Ms Stewart found clinicians had an immense need for customized design, implementation, and management of comprehensive compliance programs. "Every time I walked into a doctor's office as a surveyor, I was impressed that the doctors wanted to do their best, but they had difficulty translating the Federal Register into practical application," Ms Stewart says. "Failure to meet the regulations wasn't intentional. What placed them in a difficult situation was that they didn't know what they didn't know."

After completing her surveyor position, Ms Stewart knew she wanted to provide doctors with the tools necessary to meet requirements and maintain compliance successfully. Ms Stewart established her business to focus 100% of her time on helping clinical labs across the country. Her ability to earn her clients' loyalty is remarkable and will no doubt guarantee RPL's success for decades to come.

RPL shines in the "post trauma" of the accreditation survey; the company is able to provide a plan that responds to deficiencies, and develops and applies remedial measures. RPL is also widely known for working with start-up labs. The company provides a complete management program, staff training, and assists with the initial inspection and continuation of ongoing maintenance to ensure a high level of quality.

## FUTURE OF THE INDUSTRY: Discussion with Rochelle Stewart

Ms Stewart is very passionate about having laboratory testing under the control of the ordering health care provider. "Lab is integral to the scope of care clinicians provide their patients," she says. "In-house diagnostics provide quick answers for patients regarding diagnosis, treatment, and health maintenance decisions. Providing these services should not be an intimidating process. We can make this aspect of medical care stress-free and beneficial." Ms Stewart has seen an increase in doctors offering on-site testing and believes this trend will continue in the future.

Remote consulting is an example of how RPL is evolving to meet client needs relative to cost efficiencies and time management. RPL's Web site will soon offer products that can be accessed for download or direct order. Ms Stewart is very excited about providing this new level of service for RPL clients.

An impending challenge for 2012 will be working through the proposed Accountable Care Organizations. This is an interesting concept with challenging financial issues to solve. Not one to shy away from a challenge, Ms Stewart looks forward to working with her current and new clients to create solutions that help them succeed in this new environment.

"There are several components required to build or maintain a lab: staff, analytical equipment, laboratory information system/ electronic medical records, and supplies," Ms Stewart says. "We provide the thread to knit these items together, not only with the implementation of our programs and services but also with the knowledge and expertise of how to create a cohesive flow. I have found that when RPL is involved working in partnership with the various manufacturers and distributors, success is achieved."

Sarah Michaud is a contributing writer for CLP.

RPL Laboratory Solutions<sup>®</sup> Inc 6021 Natchez Rd Riverside, CA 92509-4947 (888) 566-5505 www.rplLaboratorySolutions.com



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Northside Hospital Tampa Saint Petersburg, Fla (727) 521-5053

Norton Community Hospital Norton, Va (276) 679-9600

**Oakwood Heritage** Hospital Taylor, Mich (313) 295-5000

**Ochsner Medical** Center Baton Rouge, La (225) 755-4825

**Ohio Cancer Specialists** Mansfield, Ohio (419) 756-2122

Omega Diagnostics LLC Shreveport, La (318) 364-2048

**Oncology &** Hematology Associates Kansas City, Mo (816) 333-1326

Paoli Hospital Paoli, Pa (610) 526-3000

**Parkview Adventist Medical Center** Brunswick, Me (207) 729-1641

Parma Community General Hospital Parma, Ohio (440) 743-3000

Pathology Associates Medical Laboratory Spokane, Wash (509) 755-8936

Pathology Services Springfield Springfield, Mo (417) 269-4647

**Peace Health** Laboratories Springfield, Ore (541) 686-7300

Pee Dee Medical Center Darlington, SC (243) 395-8436

**Pender Mercy Medical** Clinic Pender, Neb (402) 385-3033

Penn State Hershey Medical Center Hershey, Pa (717) 531-7742

**Penrose Hospital** Colorado Springs, Colo (719) 776-5816

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Medical Center

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Sacred Heart

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Edgewood, Ky (859) 301-2018

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Saint Johns Hospital

San Marcos Clinic

Fontana, Calif

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Memorial Hospital

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Pomona Valley Hospital Pomona, Calif (909) 865-9824

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Potomac Hospital Woodbridge, Va (703) 670-1347

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Prevost Memorial Hospital Donaldsonville, La

Provena Covenant Medical Center Urbana, Ill (217) 337-2000

(225) 473-7931

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**Quest Diagnostics** Baltimore (410) 536-1436

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**Reginal Cancer Center** Select Diagnostics Burlington, NC (336) 510-1120 Erie, Pa (814) 838-0458

**Regional Medical** 

Center PC

Mandan, ND

(701) 667-1000

**Regional Hospital** Sentara Healthcare Scranton, Pa (570) 348-7550 Norfolk, Va (757) 261-0267

> **Sheehan Memorial** Hospital Buffalo, NY (716) 848-2000

Shelby Memorial Hospital Laboratory Shelbyville, Ill (217) 774-3961

Shelby Regional **Medical Center** Center, Tex (936) 598-2781

**Shriners Hospital** Lexington, Ky (859) 266-2101

Sienco Instruments Morrison, Colo (303) 697-4539

**Skin Care Center** Lake Forest, Ill (847) 234-6121

**Skokie Hospital** Skokie, Ill (847) 933-6620

Skyridge Medical Center Cleveland, Tenn (423) 559-6000

Solstas Laboratory Greensboro, NC (336) 271-4950

Somerset Medical Center Somerville, NJ (908) 685-2935

South Bend Medical Foundation South Bend, Ind (800) 544-0925

**South Florida Baptist** Hospital Plant City, Fla (813) 757-8363

**South Fulton Medical** Center East Point, Ga (404) 466-1400

Southwest General Hospital San Antonio (210) 921-2000

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Southwestern Vermont Medical Center Bennington, Vt (802) 442-6361

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**St Claire Regional** Medical Center Morehead, Ky (606) 783-6500

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**St Louis Psychiatric Rehab Center** St Louis (314) 877-5989

St Luke Hospital Fort Thomas, Ky (859) 572-3100

St Lukes Cornwall Hospital Newburgh, NY (845) 561-4400

St Marys Hospital Amsterdam, NY (518) 841-3890

St Peters University Hospital New Brunswick, NJ (732) 745-8600

St Vincent Mercy Hospital Elwood, Ind (765) 552-4600

**Stevens Community Medical Center** Morris, Minn (320) 589-7672

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(269) 278-1145 **Three Rivers** Pathology Roseville, Minn (651) 635-9700

**Tisdale & Clark** Pine Bluff, Ark (870) 541-7524

**TPMG Central Lab** Newport News, Va (757) 873-0952

**Tricoare Reference** Labs Albuquerque, NM (505) 938-8855

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(248) 324-0732

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Wayne General

Twin County Regional Hospital Galax, Va (276) 236-1690

> Tyler Hematology Oncology Tyler, Tex (903) 592-6152

Unilab Inc Oak Park, III (708) 848-1556

> **Union General Hospital** Blairsville, Ga (706) 745-2111

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University of Pittsburgh Medical Center Pittsburgh (412) 623-2318

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Upstate Medical Center Pathology Syracuse, NY (315) 464-4750

University of Wisconsin Medical Foundation Madison, Wis (608) 287-2110

Valdosta Medical Clinic Valdosta, Ga (229) 242-8480

Valley Medical Center PLLC Lewiston, Idaho (208) 298-3101

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Veterans Affairs Medical Center Poplar Bluff, Mo (573) 778-4643

Virginia Beach **General Hospital** Virginia Beach, Va (757) 395-8059